

REMARKS

Reconsideration and allowance in view of the foregoing amendments and the following remarks are respectfully requested.

Claims 1-32 remain pending in the present application.

Attached hereto is a marked-up version of the changes made to the claims. The attached pages are entitled "Version With Markings to Show Changes Made." In addition, a complete set of the pending claims, including the present amendments, entitled "Complete Set Of Pending Claims" is submitted herewith for the Examiner's convenience.

Applicant notes with appreciation the Examiner's indication that claim 6 would be allowable if rewritten in independent form. At this time, the Examiner's suggestion has not been adopted, because the base claim from which claim 6 depends is believed to be patentable over the cited references for the reasons presented below.

I. Acknowledgement of Priority Claim

The present application claims priority under 35 U.S.C. § 119(e) from U.S. provisional patent application no. 60/139,424 filed June 15, 1999. The Examiner's attention is directed to the Inventors' Declaration submitted with the original filing papers in which this priority claim is made. The specification, as amended on August 8, 2002, makes specific reference to the priority document. Accordingly, Applicant respectfully requests acknowledgment of the priority claim.

II. Rejection of the Claims Based on the Cited References

Claims 1-4, 13, 14, 16-25, 27 and 30-32 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,041,780 to Richard et al. ("the '780 patent"). In addition, claims 5, 7-12, 15, 26, 28, and 29 stand rejected under 35 U.S.C. § 103 as being unpatentable over the '780 patent. Applicant respectfully traverses this rejection for the reasons presented below.

The present invention pertains to a method or apparatus that adjusts an inspiratory positive airway pressure ("IPAP") of a fluid supplied to a patient. This method includes determining, for each inspiratory phase, a volume of fluid received by such a patient. This volume of fluid received by a patient during the inspiratory phase of the respiratory cycle is typically referred to by those skilled in the art as the "tidal volume". The present invention then determines an average of the tidal volumes received by such a patient during a plurality respiratory cycles. Each of the independent claims in the present application has been amended above to clarify that the "average of the tidal volumes" is determined irrespective of a period of time during which the plurality of inspiratory phases occur. This average tidal volume is then compared to a predetermined target tidal volume, and IPAP level is then adjusted based on the comparison.

The '780 patent uses a parameter known as "minute volume" to control the IPAP level. By definition, determining "minute volume" requires determining the number of breaths over a one minute period, also known as the breath rate. The sum of the tidal volumes over the number of breaths that the patient would have in a one minute period is the "minute volume",

i.e., the total volume of air respired over the course of a minute. See, column 3, lines 3-7, and column 4, lines 17-21, of the '780 patent. The present invention, on the other hand, recites that the average tidal volume is determined irrespective of a period of time during which the plurality of inspiratory phases occur. Thus, the present invention does not include the additional step of calculating the number of breaths occurring in the one minute period, i.e., the breathing rate, as required in the '780 patent. See step 46 in Fig. 2A of the '780 patent. As noted in the previous Amendment dated August 8, 2002, the use of average tidal volume provides significant benefits over using minute ventilation that are not taught or suggested by the references of record.

For the reasons presented above, applicant respectfully submit that independent claims 1, 7, 13, 19, 23, and 27 are not anticipated or rendered obvious by the cited references. In addition, claims 2-5, 8-12, 14-18, 20-22, 24-26 and 28-32 are also not anticipated or rendered obvious due to their dependency from one of the above-noted independent claims. Accordingly, applicant respectfully requests that the above rejection of these claims be withdrawn.

All rejections have been addressed. It is respectfully submitted that the present application is in condition for allowance and a Notice to the effect is earnestly solicited.

Respectfully submitted,

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Attached: 1) Marked-up version of the title, abstract specification, and claims entitled, "Version With Markings to Show Changes Made"; and
2) Copy of Presently Pending Claims (including present amendments).

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 1, 7, 8, 13, 19, 23, 27, and 28 have been amended as follows:

1. (Twice Amended) A method of adjusting a volume of a fluid supplied to a patient, the method comprising the steps of:

(a) supplying a plurality of volumes of fluid to a patient during a like plurality of inspiratory phases of a respiratory cycle of such a patient, each volume of fluid being supplied at an inspiratory positive airway pressure during a corresponding inspiratory phase;

(b) determining, for each inspiratory phase, a tidal volume of fluid received by such a patient;

(c) determining an average tidal volume of fluid received by such a patient from the volumes of fluid received by such a patient during the plurality of inspiratory phases, wherein the average tidal volume is determined irrespective of a period of time during which the plurality of inspiratory phases occur;

(d) comparing the average tidal volume to a predetermined target tidal volume;

and

(e) adjusting the inspiratory positive airway pressure based on the comparison.

7. (Twice Amended) A method of supplying fluid to a patient, comprising:

(a) supplying a first volume of fluid to a patient at a first inspiratory positive airway pressure;

(b) determining, for the first volume of fluid supplied to such a patient, a first tidal volume of fluid received by such a patient;

(c) supplying a second volume of fluid to such a patient at the first inspiratory positive airway pressure;

(d) determining, for the second tidal volume of fluid supplied to such a patient, a second volume of fluid received by such patient;

(e) determining, based on the first and the second tidal volumes of fluid received by such a patient, a first average tidal volume of fluid received by such patient, wherein the first average tidal volume is determined irrespective of a period of time during which the plurality of inspiratory phases occur;

(f) comparing the first average tidal volume to a predetermined target tidal volume; and

(g) adjusting the first inspiratory positive airway pressure to a second inspiratory positive airway pressure based on the comparison in comparing step (f).

8. (Twice Amended) The method as set forth in claim 7, further comprising:

(h) supplying a third volume of fluid to such a patient at the second inspiratory positive airway pressure;

(i) determining, for the third tidal volume of fluid supplied to such a patient, a third volume of fluid received by such a patient;

(j) determining, based on the second and the third tidal volumes of fluid received by such a patient, a second average tidal volume of fluid received by such a patient, wherein the second average tidal volume is determined irrespective of a period of time during which the plurality of inspiratory phases occur;

(k) comparing the second average tidal volume to the predetermined target tidal volume; and

(l) adjusting the second inspiratory positive airway pressure to a third inspiratory positive airway pressure based on the comparison in comparing step (k).

13. (Twice Amended) An apparatus for supplying fluid to a patient, the apparatus comprising:

a pressure generating system adapted to provide a flow of fluid at one of a variable pressure and a variable flow;

a patient circuit operatively coupled to the pressure generating system to deliver the flow of fluid to a patient;

an interface device operatively coupled to the patient circuit to communicate the flow of fluid to an airway of a patient;

at least one sensor operatively coupled to one of the pressure generating system, the patient circuit, and the interface device to detect a parameter indicative of a volume of fluid delivered to such a patient; and

a controller operatively coupled to the sensor and the pressure generating system, wherein the controller:

(a) determines, for each inspiratory phase of a respiratory cycle of such a patient, a tidal volume of fluid received by such a patient based on the parameter indicative of a volume of fluid delivered to such a patient provided by the sensor;

(b) determines an average tidal volume of fluid received by such a patient over a plurality of inspiratory phases, wherein the average tidal volume is determined irrespective of a period of time during which the plurality of inspiratory phases occur;

(c) compares the average tidal volume of fluid received by such a patient to a predetermined target tidal volume; and

(d) causes the pressure generating system to adjust one a pressure and a rate of flow of fluid output thereby based on the comparison.

19. (Twice Amended) An apparatus for supplying fluid to a patient, the apparatus comprising:

pressure generating means for providing a flow of fluid at one of a variable pressure and a variable flow rate;

delivering means for delivering the flow of fluid to a patient;

interfacing means for communicating the flow of fluid to an airway of a patient;

sensing means for sensing a parameter indicative of a volume of fluid delivered to such a patient; and

processing means for:

(a) determining, for each inspiratory phase of a respiratory cycle of such a patient, a tidal volume of fluid received by such a patient based on the parameter indicative of a volume of fluid delivered to such a patient provided by the sensing means;

(b) determining an average tidal volume of fluid received by such a patient over a plurality of inspiratory phases, wherein the average tidal volume is determined irrespective of a period of time during which the plurality of inspiratory phases occur;

(c) comparing the average tidal volume of fluid received by such a patient to a predetermined target tidal volume; and

(d) causing the pressure generating means to adjust at least one of a pressure and a rate of flow of fluid output thereby based on the comparison.

23. (Twice Amended) An apparatus for adjusting a volume of a fluid supplied to a patient, the apparatus comprising:

supplying means for supplying a plurality of volumes of fluid to a patient during a like plurality of inhalations by such a patient, with each volume of fluid supplied at an inspiratory positive airway pressure during a corresponding inspiratory phase;

tidal volume determining means for determining, for each inspiratory phase, a tidal volume of fluid received by such a patient;

average tidal volume determining means for determining an average tidal volume of fluid received by such a patient from the tidal volumes of fluid received by such a patient during the plurality of inspiratory phases, wherein the average tidal volume is determined irrespective of a period of time during which the plurality of inspiratory phases occur;

comparing means for comparing the average tidal volume to a predetermined target tidal volume; and

adjusting means for adjusting the inspiratory positive airway pressure based on the comparison.

23. (Twice Amended) An apparatus for adjusting a volume of a fluid supplied to a patient, the apparatus comprising:

supplying means for supplying a plurality of volumes of fluid to a patient during a like plurality of inhalations by such a patient, with each volume of fluid supplied at an inspiratory positive airway pressure during a corresponding inspiratory phase;

tidal volume determining means for determining, for each inspiratory phase, a tidal volume of fluid received by such a patient;

average tidal volume determining means for determining an average tidal volume of fluid received by such a patient from the tidal volumes of fluid received by such a patient during the plurality of inspiratory phases, wherein the average tidal volume is determined irrespective of a period of time during which the plurality of inspiratory phases occur;

comparing means for comparing the average tidal volume to a predetermined target tidal volume; and

adjusting means for adjusting the inspiratory positive airway pressure based on the comparison.

**COMPLETE SET OF PENDING CLAIMS
(Including the Present Amendments)**

1. (Twice Amended) A method of adjusting a volume of a fluid supplied to a patient, the method comprising the steps of:

(a) supplying a plurality of volumes of fluid to a patient during a like plurality of inspiratory phases of a respiratory cycle of such a patient, each volume of fluid being supplied at an inspiratory positive airway pressure during a corresponding inspiratory phase;

(b) determining, for each inspiratory phase, a tidal volume of fluid received by such a patient;

(c) determining an average tidal volume of fluid received by such a patient from the volumes of fluid received by such a patient during the plurality of inspiratory phases, wherein the average tidal volume is determined irrespective of a period of time during which the plurality of inspiratory phases occur;

(d) comparing the average tidal volume to a predetermined target tidal volume;
and

(e) adjusting the inspiratory positive airway pressure based on the comparison.

2. (Amended) The method as set forth in claim 1, wherein step (b) includes:

estimating, for each inspiratory phase, a volume of fluid leaked from a breathing gas supply system that supplies such a patient with the plurality of volumes of fluid; and

combining, for each inspiratory phase, the volume of fluid leaked and the volume of fluid supplied to such a patient to obtain the tidal volume of fluid received by such a patient.

3. (Amended) The method as set forth in claim 1, wherein step (e) includes:

increasing the inspiratory positive airway pressure responsive to the average tidal volume being is less than a predetermined target tidal volume;

decreasing the inspiratory positive airway pressure responsive to the average tidal volume being greater than the predetermined target tidal volume; and

maintaining the inspiratory positive airway pressure responsive to the average tidal volume being within a predetermined offset volume of the predetermined target tidal volume.

4. The method as set forth in claim 3, wherein the inspiratory positive airway pressure is one of (a) increased and (b) decreased by a predetermined pressure.

5. The method as set forth in claim 4, wherein the predetermined pressure is approximately 0.1 cm H₂O.

6. The method as set forth in claim 1, further comprising:
comparing a current inspiratory positive airway pressure to a maximum inspiratory positive airway pressure and a minimum inspiratory positive airway pressure; and
preventing adjusting of the inspiratory positive airway pressure in step (e) if one of (1) the current inspiratory positive airway pressure is greater than the maximum inspiratory positive airway pressure and (2) the current inspiratory positive airway pressure is less than the minimum inspiratory positive airway pressure.

7. (Twice Amended) A method of supplying fluid to a patient, comprising:
(a) supplying a first volume of fluid to a patient at a first inspiratory positive airway pressure;
(b) determining, for the first volume of fluid supplied to such a patient, a first tidal volume of fluid received by such a patient;
(c) supplying a second volume of fluid to such a patient at the first inspiratory positive airway pressure;
(d) determining, for the second tidal volume of fluid supplied to such a patient, a second volume of fluid received by such patient;

(e) determining, based on the first and the second tidal volumes of fluid received by such a patient, a first average tidal volume of fluid received by such patient, wherein the first average tidal volume is determined irrespective of a period of time during which the plurality of inspiratory phases occur;

(f) comparing the first average tidal volume to a predetermined target tidal volume; and

(g) adjusting the first inspiratory positive airway pressure to a second inspiratory positive airway pressure based on the comparison in comparing step (f).

8. (Twice Amended) The method as set forth in claim 7, further comprising:

(h) supplying a third volume of fluid to such a patient at the second inspiratory positive airway pressure;

(i) determining, for the third tidal volume of fluid supplied to such a patient, a third volume of fluid received by such a patient;

(j) determining, based on the second and the third tidal volumes of fluid received by such a patient, a second average tidal volume of fluid received by such a patient, wherein the second average tidal volume is determined irrespective of a period of time during which the plurality of inspiratory phases occur;

(k) comparing the second average tidal volume to the predetermined target tidal volume; and

(l) adjusting the second inspiratory positive airway pressure to a third inspiratory positive airway pressure based on the comparison in comparing step (k).

9. The method as set forth in claim 8, wherein at least two of the first, the second, and the third inspiratory positive airway pressures are the same.

10. (Amended) The method as set forth in claim 7, wherein the second inspiratory positive airway pressure is greater than the first inspiratory positive airway pressure

responsive to the first average tidal volume being less than the predetermined target tidal volume, and wherein the second inspiratory positive airway pressure is less than the first inspiratory positive airway pressure responsive to the first average tidal volume being greater than the predetermined target tidal volume.

11. (Amended) The method as set forth in claim 7, wherein the second inspiratory positive airway pressure is the same as the first inspiratory positive airway pressure responsive to the first average tidal volume being within a predetermined offset volume of the predetermined target tidal volume.

12. The method as set forth in claim 7, wherein at least one of the first volume of fluid received by such a patient and the second volume of fluid received by such a patient is determined by performing one of (1) leak estimation and (2) regression analysis, and wherein the leak estimation includes:

estimating a volume of fluid leaked from a breathing gas supply system that supplies such a patient with the first and the second volumes of fluid; and

combining the volume of fluid leaked and the volume of fluid supplied to such a patient to obtain the volume of fluid received by such a patient.

13. (Twice Amended) An apparatus for supplying fluid to a patient, the apparatus comprising:

a pressure generating system adapted to provide a flow of fluid at one of a variable pressure and a variable flow;

a patient circuit operatively coupled to the pressure generating system to deliver the flow of fluid to a patient;

an interface device operatively coupled to the patient circuit to communicate the flow of fluid to an airway of a patient;

at least one sensor operatively coupled to one of the pressure generating system, the patient circuit, and the interface device to detect a parameter indicative of a volume of fluid delivered to such a patient; and

a controller operatively coupled to the sensor and the pressure generating system, wherein the controller:

(a) determines, for each inspiratory phase of a respiratory cycle of such a patient, a tidal volume of fluid received by such a patient based on the parameter indicative of a volume of fluid delivered to such a patient provided by the sensor;

(b) determines an average tidal volume of fluid received by such a patient over a plurality of inspiratory phases, wherein the average tidal volume is determined irrespective of a period of time during which the plurality of inspiratory phases occur;

(c) compares the average tidal volume of fluid received by such a patient to a predetermined target tidal volume; and

(d) causes the pressure generating system to adjust one a pressure and a rate of flow of fluid output thereby based on the comparison.

14. (Amended) The apparatus as set forth in claim 13, wherein the controller causes the pressure generating system to:

(e) increase one of a pressure and a rate of the flow of fluid output by the pressure generating system responsive to the average tidal volume of fluid being less than the predetermined target tidal volume;

(g) decrease one of a pressure and rate of the flow of fluid output by the pressure generating system responsive to the average tidal volume of being greater than the predetermined target tidal volume; and

(g) maintain one of a pressure and a rate of the flow of fluid output by the pressure generating system responsive to the average tidal volume of fluid being within a predetermined offset volume of the predetermined target tidal volume.

15. An apparatus as set forth in claim 13, wherein the controller prevents adjusting one of a pressure and rate of flow of fluid output by the pressure generating system if one of (a) the current pressure is greater than a predetermined maximum pressure and (b) the current pressure is less than a predetermined minimum pressure.

16. An apparatus as set forth in claim 13, wherein the pressure generating system includes:

a fluid source that outputs the flow of fluid at one of a predetermined pressure and a predetermined flow rate; and

a pressure/flow regulator operatively coupled to the pressurized fluid source to vary one of a pressure and a rate of flow of the flow of fluid output by the fluid source.

17. (Amended) An apparatus as set forth in claim 13, wherein the at least one sensor includes a flow sensor adapt to detect a rate of flow of fluid in the patient circuit as the parameter indicative of a volume of fluid delivered to such a patient, and a pressure sensor adapted to detect a pressure at which the fluid is supplied to such a patient, and wherein the controller estimates:

(a) a volume of fluid leaked to atmosphere based on a pressure at which the fluid is supplied to the patient measured by the pressure sensor,

(b) a tidal volume of fluid received by such patient based on a difference between the volume of fluid supplied to such patient and the volume of fluid leaked to atmosphere;

(c) an average tidal volume of fluid received by such a patient during each inhalation based on tidal volumes of fluid received by such a patient during a plurality of inhalations; and

(d) a difference between the average tidal volume and the predetermined target tidal volume.

18. (Amended) An apparatus as set forth in claim 13, wherein the controller causes the pressure generating system to adjust one of the pressure and the flow of fluid supplied to the patient as a function of a moving average of the tidal volumes of fluid received by the patient.

19. (Twice Amended) An apparatus for supplying fluid to a patient, the apparatus comprising:

pressure generating means for providing a flow of fluid at one of a variable pressure and a variable flow rate;

delivering means for delivering the flow of fluid to a patient;

interfacing means for communicating the flow of fluid to an airway of a patient;

sensing means for sensing a parameter indicative of a volume of fluid delivered to such a patient; and

processing means for:

(a) determining, for each inspiratory phase of a respiratory cycle of such a patient, a tidal volume of fluid received by such a patient based on the parameter indicative of a volume of fluid delivered to such a patient provided by the sensing means;

(b) determining an average tidal volume of fluid received by such a patient over a plurality of inspiratory phases, wherein the average tidal volume is determined irrespective of a period of time during which the plurality of inspiratory phases occur;

(c) comparing the average tidal volume of fluid received by such a patient to a predetermined target tidal volume; and

(d) causing the pressure generating means to adjust at least one of a pressure and a rate of flow of fluid output thereby based on the comparison.

20. (Amended) An apparatus as set forth in claim 19, wherein the processing means further determines:

a volume of fluid leaked into atmosphere as a function of the pressure at which the fluid is supplied to the patient;

a tidal volume of fluid received by the patient as a function of a difference between the volume of fluid supplied to the patient and the volume of fluid leaked into atmosphere;

an average tidal volume of fluid received by such a patient during each an inspiratory phase based on tidal volumes of fluid received by the patient during a plurality of inspiratory phases; and

a difference between the average tidal volume of fluid and the predetermined target tidal volume.

21. (Amended) An apparatus as set forth in claim 19, wherein the processing means causes the pressure generating means to:

(e) increase one of a pressure and a rate of flow at which the fluid is supplied to the patient responsive to the average tidal volume of fluid supplied to the patient being less than the predetermined target tidal volume;

(f) decrease one of a pressure and a rate of flow at which the fluid is supplied to the patient responsive to the average tidal volume of fluid supplied to the patient being greater than the predetermined target tidal volume; and

(g) maintain one of a pressure and a rate of flow at which the fluid is supplied to the patient responsive to the average tidal volume of fluid supplied to the patient being within an offset volume of the predetermined target tidal volume.

22. (Amended) An apparatus as set forth in claim 19, wherein the processing means causes the pressure generating means to adjust one of a pressure and a flow of the fluid supplied to the patient as a function of a moving average of the tidal volumes of fluid received by the patient.

23. (Twice Amended) An apparatus for adjusting a volume of a fluid supplied to a patient, the apparatus comprising:

supplying means for supplying a plurality of volumes of fluid to a patient during a like plurality of inhalations by such a patient, with each volume of fluid supplied at an inspiratory positive airway pressure during a corresponding inspiratory phase;

tidal volume determining means for determining, for each inspiratory phase, a tidal volume of fluid received by such a patient;

average tidal volume determining means for determining an average tidal volume of fluid received by such a patient from the tidal volumes of fluid received by such a patient during the plurality of inspiratory phases, wherein the average tidal volume is determined irrespective of a period of time during which the plurality of inspiratory phases occur;

comparing means for comparing the average tidal volume to a predetermined target tidal volume; and

adjusting means for adjusting the inspiratory positive airway pressure based on the comparison.

24. (Amended) The apparatus as set forth in claim 23, wherein the tidal volume determining means includes:

leak estimating means for estimating, for each inspiratory phase, a volume of fluid leaked from the supplying means; and

combining means for combining, for each inspiratory phase, the volume of fluid leaked and the volume of fluid supplied to the patient to obtain the tidal volume of fluid received by the patient.

25. (Amended) The apparatus as set forth in claim 23, wherein the adjusting means:

increases the inspiratory positive airway pressure responsive to the average tidal volume being less than a predetermined target tidal volume;

decreases the inspiratory positive airway pressure responsive to the average tidal volume being greater than the predetermined target tidal volume; and
maintains the inspiratory positive airway pressure responsive to the average tidal volume being within a predetermined offset volume of the predetermined target tidal volume.

26. The apparatus as set forth in claim 23, further comprising:

comparing means for comparing a current inspiratory positive airway pressure to a maximum inspiratory positive airway pressure and a minimum inspiratory positive airway pressure; and

preventing means for preventing adjusting of the inspiratory positive airway pressure if one of (1) the current inspiratory positive airway pressure is greater than the maximum inspiratory positive airway pressure and (2) the current inspiratory positive airway pressure is less than the minimum inspiratory positive airway pressure.

23. (Twice Amended) An apparatus for adjusting a volume of a fluid supplied to a patient, the apparatus comprising:

supplying means for supplying a plurality of volumes of fluid to a patient during a like plurality of inhalations by such a patient, with each volume of fluid supplied at an inspiratory positive airway pressure during a corresponding inspiratory phase;

tidal volume determining means for determining, for each inspiratory phase, a tidal volume of fluid received by such a patient;

average tidal volume determining means for determining an average tidal volume of fluid received by such a patient from the tidal volumes of fluid received by such a patient during the plurality of inspiratory phases, wherein the average tidal volume is determined irrespective of a period of time during which the plurality of inspiratory phases occur;

comparing means for comparing the average tidal volume to a predetermined target tidal volume; and

adjusting means for adjusting the inspiratory positive airway pressure based on the comparison.

29. The apparatus as set forth in claim 28, wherein at least two of the first, second and third inspiratory positive airway pressures are the same.

30. (Amended) The apparatus as set forth in claim 27, wherein the second inspiratory positive airway pressure is greater than the first inspiratory positive airway pressure responsive to the first average tidal volume being less than the predetermined target tidal volume, and wherein the second inspiratory positive airway pressure is less than the first inspiratory positive airway pressure responsive to the first average tidal volume being greater than the predetermined target tidal volume.

31. (Amended) The apparatus as set forth in claim 27, wherein the second inspiratory positive airway pressure is the same as the first inspiratory positive airway pressure responsive to the first average tidal volume being within a predetermined offset volume of the predetermined target tidal volume.

32. (Amended) The apparatus as set forth in claim 27, further comprising leak estimating means for determining at least one of the first tidal volume of fluid received by the patient and the second tidal volume of fluid received by the patient by performing one of (a) leak estimation and (b) regression analysis, and wherein the leak estimating performs leak estimation by:

(1) estimating a volume of fluid leaked from the supplying means; and

(2) combining the volume of fluid leaked from the supplying means and the volume of fluid supplied to such a patient to obtain the volume of fluid received by such a patient.